Claims

1. A method of using ultrasound waves focused at a specific location in a medium to cause localized production of bubbles at said location, to control said production, and to control the cavitational and heating effects that take place at said location; wherein, said production and control is accomplished by selecting the range of parameters of multiple transducers focused at said location in order to produce one of the waveforms chosen from the following group:
   - a waveform comprising high negative peaks and small positive peaks, said waveform encouraging the creation of a cloud of microbubbles;
   - a waveform encouraging the production of heat and the limitation the growth and possible implosion of said microbubbles; and
   - a combined waveform comprising a spatial and/or temporal combination of two waveforms - one waveform comprising high negative peaks and small positive peaks and the second waveform comprising high positive peaks and only small negative peaks, said combined waveform allowing control of the size distribution of the microbubbles and temporal changes of this distribution.

2. A method according to claim 1, wherein the waveform encouraging the production of heat is chosen from the group comprising:
   - a waveform comprising high positive peaks and only small negative peaks; and

– a sinusoidal waveform.

3. A method according to claim 2, wherein the waveform comprising high positive peaks and only small negative peaks encourages the reduction of the size of said microbubbles.

4. A method according to claim 1, wherein the number of transducers is three.

5. A method according to claim 1, wherein the radius of the microbubbles is in the range from a fraction of a micron up to 100 or more microns, preferably between approximately 3 microns to 5 microns.

6. A method according to claim 1, wherein a control system measures the changes in tissue or the bubbles size and accordingly adjusts the waveform to include more negative peaks, more positive peaks, or more equal sized waves.

7. A method according to claim 1, wherein a temperature control system is used to modify the output of the transducers according to the measured temperature.

8. A method according to claim 1, wherein an ultrasound imaging or non-imaging system is used to view and monitor the region being targeted, to monitor the generation of the microbubbles at the desired location, and control the system for one or more of the following purposes:
   - so that the number of microbubbles will be as planned;
   - for aiming the focused beam to the targeted location; and
   - to re-align the beam to a different location.

9. A method according to claim 8, wherein the response at the half harmonic or at higher harmonics of the transmitted frequencies is used by the ultrasound imaging or non-imaging system to measure one or more of the following:
   - the effect of the heating;
   - the duration of said effect;
   - the number of microbubbles generated within the targeted region; and
   - the spatial distribution of said microbubbles generated within said targeted region.

10. A method according to claim 1, wherein the multiple transducers are arranged as an array, designed so that their mechanical focus and their own focus combine at the same point in space.

11. A method according to claim 10, wherein the point in space can be moved by either shifting the whole array, by repositioning of individual transducers, or by phase shift of the excitation pulse.

12. A method according to claim 10, wherein the ultrasonic waves transmitted by the different transducers are designed to produce by interference specific waveforms at the focal point, which are not produced at other locations.

13. A method according to claim 12, wherein the specific waveforms can be modified to produce one of the following effects:

- cause cavitation with no significant change in temperature;
- increase the temperature with minimal cavitation;
- suppress cavitation; and
- a combination of these effects.

14. A method according to claim 12, wherein the region within the focal zone of all the transducers in which the specific waveform develops at significant intensities and the amplitudes of the waveforms are less than –3 DB of the maximum amplitude, are typically at distances less than 25mm and preferably less than 1 mm away from the point of said maximum amplitude in the lateral directions and less than 10mm and preferably less than 1.5 mm away in the axial directions.

15. A method according to claim 1, wherein the localized production of bubbles at the location and control of the cavitational and heating effects that take place at said location are for therapeutic purposes.

16. A method according to claim 1, wherein the array is placed extra-corporally, in close proximity to the organ to be treated, with ultrasound gel or water surrounding the ultrasound transducers and the space between it and the organ.

17. A method according to claim 15, wherein the therapy is chosen from the following group:

- occlusion of varicose veins and telangiectasia;
- activation of cellular (e.g. endothelial cell) processes in the body, by either localized pressure forces or shear forces that produce therapeutic responses or damage;
- therapy of cancerous tissue by cavitation damage and/or rapid hyperthermia, resulting in apoptosis, tissue ablation or necrosis;
- therapy of cancerous tissue by damage and closure of the supply and drainage vasculature by cavitation, and/or rapid hyperthermia via coagulation of the arteries supplying the tumor;
- ablation of ectopic foci or re-entry loops within the cardiac walls, mainly within the ventricular walls;

- thrombolysis of clotted or semi-clotted arteries, e.g. coronary arteries, the carotid arteries, cerebral arteries, peripheral arteries etc.
- lipolysis or other methods of disintegration of fat cells, either by the mechanism of microbubbles collapse and/or by hyperthermia, resulting in apoptosis and drainage of fat deposits;
- coagulation of internal bleedings within the body; and
- non-invasive surgery of internal tissues and organs, by disintegration of cells along the cut.

18. A method of occlusing varicose veins and telangiectasia according to claim 17, comprising the steps of:

a) providing multiple transducers;

b) focusing said multiple transducers at the same location within said vein;

c) selecting the range of parameters of said multiple transducers to produce a waveform comprising high negative peaks and small positive peaks, said waveform encouraging the creation of a cloud of microbubbles;

d) continuing the production of the waveform until the cavitation causes destruction of cells and the initiation of scaring of the tissue at said location;

e) focusing said transducers at another location within said vein;

f) repeating steps (c), (d), and (e) until enough scaring has been initiated to cause occlusion of said vein.

19. A method according to claim 18, wherein two additional steps are added between steps (d) and (e), said steps comprising:

g) changing the range of parameters of the multiple transducers to produce a heating waveforms, said waveform encouraging the production of heat at the location; and

h) continuing the production of the waveform until the heating causes destruction of cells and the initiation of scaring of the tissue at said location.

20. A method according to claim 17, wherein activation of cellular processes in the body produces therapeutic responses or damage selected from the following group: localized drug delivery, gene therapy, and angiogenesis.

21. A method according to claim 17, wherein thrombolysis of clotted or semi-clotted arteries is performed in arteries chosen from the group comprising: coronary arteries, the carotid arteries, cerebral arteries, and peripheral arteries.

22. A system for carrying out the method of claim 1, said system comprising:

– three or more arbitrary waveform signal generators;

- three or more wide-band power amplifiers;
- three or more transducers; and
- one workstation.

23. A system according to claim 22, wherein the three or more transducers are arranged as an array, designed so that their mechanical focus and their own focus combine at the same point in space.

24. A system according to claim 23, wherein the point in space can be moved by either shifting the whole array, by repositioning of individual transducers, or by phase shift of the excitation pulse.

25. A system according to claim 23, wherein the ultrasonic waves transmitted by the three or more transducers are designed to produce by interference specific waveforms at the focal point, which are not produced at other locations.

26. A system according to claim 25, wherein the specific waveforms can be modified to produce one of the following effects:
- cause cavitation with no significant change in temperature;
- increase the temperature with minimal cavitation;
- suppress cavitation; and
- a combination of these effects.

27. A system according to claim 25, wherein the region within the focal zone of all the transducers in which the specific waveform develops at significant intensities and the amplitudes of the waveforms are less than –3 DB of the maximum amplitude, are typically at distances less than 25mm and preferably less than 1 mm away from the point of said maximum amplitude in the lateral directions and less than 10mm and preferably less than 1.5 mm away in the axial directions..

28. A system according to claim 22, further comprising an ultrasound imaging or non-imaging system and a control box.

29. A system according to claim 28 wherein the ultrasound imaging or non-imaging system is used to view and monitor the region being targeted, to monitor the generation of the microbubbles at the desired location, and control the system for one or more of the following purposes:
- so that the number of microbubbles will be as planned;
- for aiming the focused beam to the targeted location; and
- to re-align the beam to a different location.

30. A system according to claim 28, wherein the response at the half harmonic or at higher harmonics of the transmitted frequencies is used

by the ultrasound imaging or non-imaging system to measure one or more of the following:

- the effect of the heating;
- the duration of said effect;
- the number of microbubbles generated within the targeted region; and
- the spatial distribution of said microbubbles generated within said targeted region.

31. A system according to claim 28, wherein the ultrasound imaging or non-imaging system is controlled by the workstation to which it is connected through the control box.

32. A system according to claim 28, wherein the ultrasound imaging or non-imaging system measures the changes in tissue or the bubbles size and the control box and workstation accordingly adjust the waveform to include more negative peaks, positive peaks or equal sized waves.

33. A system according to claim 22, further comprising a temperature measurement system.

34. A system according to claim 33, wherein the temperature measurement system comprises one or more thermocouples.

35. A system according to claim 33, wherein the temperature measurement system is used to modify the output of the transducers according to the measured temperature.

36. A system according to claim 22, adapted for use in therapeutic procedures; wherein the array is placed extra-corporally, in close proximity to the organ to be treated, with ultrasound gel or water surrounding the ultrasound transducers and the space between it and the organ.

37. A system according to claim 36, wherein the therapeutic procedure is chosen from the following group:

- occlusion of varicose veins and telangiectasia;
- activation of cellular (e.g. endothelial cell) processes in the body, by either localized pressure forces or shear forces that produce therapeutic responses or damage;
- therapy of cancerous tissue by cavitation damage and/or rapid hyperthermia, resulting in apoptosis, tissue ablation or necrosis;
- therapy of cancerous tissue by damage and closure of the supply and drainage vasculature by cavitation, and/or rapid hyperthermia via coagulation of the arteries supplying the tumor;

- ablation of ectopic foci or re-entry loops within the cardiac walls, mainly within the ventricular walls;
- thrombolysis of clotted or semi-clotted arteries, e.g. coronary arteries, the carotid arteries, cerebral arteries, peripheral arteries etc.
- lipolysis or other methods of disintegration of fat cells, either by the mechanism of microbubbles collapse and/or by hyperthermia, resulting in apoptosis and drainage of fat deposits;
- coagulation of internal bleedings within the body; and
- non-invasive surgery of internal tissues and organs, by disintegration of cells along the cut.